

REMARKS

Claims 1-16 are pending.

I. Rejection under 35 USC §103

Claims 1-10 and 12-16 are rejected under 35 USC §103(a) as being allegedly unpatentable over McDonald et al. in view of Bertz et al.

Applicant submits the above references are obviated in view of the Declaration of record. Specifically, the suggestion by Examiner that one of skill in the art would have naturally extended the length of treatment is rebutted by the Declaration from the Applicant, who also happens to be the author of the subject publication raised as alleged prior art. Dr. McDonald stated that, "one of the main reasons for ceasing treatment at 29 days was due to the potential for the occurrence of the risks associated with long term glucocorticoid administration." (McDonald Declaration, paragraph 6.) Furthermore, Bertz et al. is now obviated, as the claims now read on beclomethasone dipropionate, rather than the genus "topical active corticosteroid". Accordingly, as Bertz et al. describes treatment using budesonide, Applicant respectfully submits the present claims are free of the prior art of record.

Furthermore, Applicant contends that the Declaration of record makes clear that the intention of one skilled in art would not have found it appropriate to extend the study beyond 29 days due to the then understood risk of side effects associated with long-term corticosteroid administration. Additionally, Bertz et al. uses a completely different corticosteroid in their study, with

its own set of particularities and unique parameters. Applicant submits that it is usually quite difficult to observe experimental data using one drug and expect the same or similar data using a different drug. Not only are there likely divergent physiological processes at play, but there is the additional complexity of the systemic methylprednisolone dosing in Bertz et al. Applicant contends that it is not reasonable to assume one skilled in the art, after reading Bertz et al., would be motivated to combine the study with the parameters disclosed in McDonald et al.


II. Conclusion

Applicant respectfully requests Examiner withdraw the outstanding rejections of record and permit the claims to proceed to allowance. Applicant is filing this response concurrently with a petition for a three month extension of time and the relevant fees. If there are any questions or comments, Applicant's attorney may be reached at the telephone number state below.

Respectfully submitted,

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Date

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